Exhibit 40

State of California ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Labs, Inc. et al., Civil Action No. 03-11226-PBS

Exhibit to the November 25, 2009 Declaration of Philip D. Robben in Support of Defendants' Joint Motion for Partial Summary Judgment

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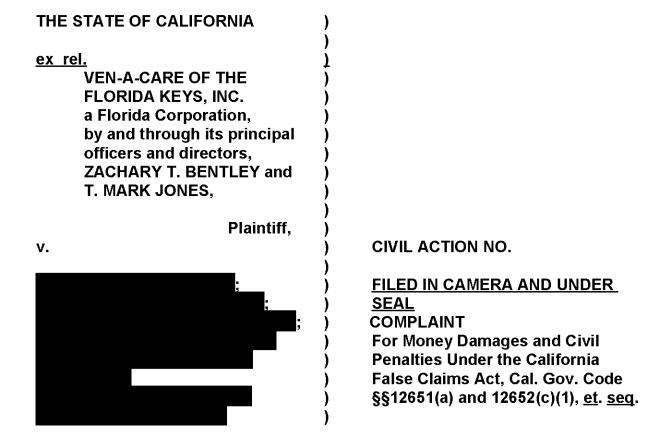
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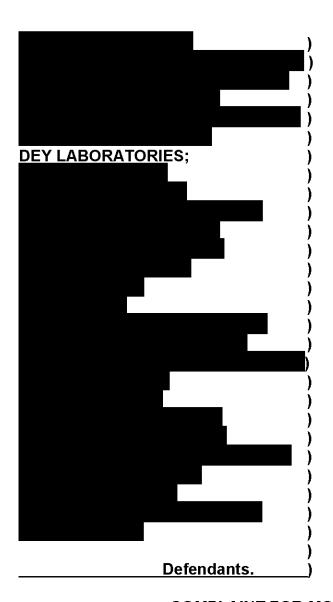
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Attorneys for the Plaintiffs, THE STATE OF CALIFORNIA <u>Ex Rel</u> The Qui Tam Plaintiff

IN THE SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE CITY AND COUNTY OF SAN DIEGO





COMPLAINT FOR MONEY DAMAGES AND CIVIL PENALTIES UNDER THE CALIFORNIA FALSE CLAIMS ACT CAL. GOV. CODE §§12651(a) AND 12652(c)(1), et. seq.

COMES NOW, the STATE OF CALIFORNIA ("GOVERNMENT" or "STATE"), by and through and in their own persons VEN-A-CARE OF THE FLORIDA KEYS, INC., a Florida corporation, by and through its principal officers and directors, ZACHARY T. BENTLEY and T. MARK JONES ("VEN-A-CARE" or "VAC"), as the "Qui Tam Plaintiff"

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and by the undersigned attorneys on behalf of the STATE OF CALIFORNIA and on the
Qui Tam Plaintiff's own behalf and bring this action against
DEY
LABORATORIES;

(sometimes referred to collectively as, "DEFENDANT PHARMACEUTICAL MANUFACTURERS"), for money damages and civil penalties arising out of the DEFENDANT PHARMACEUTICAL MANUFACTURERS' violations of the California False Claims Act, Cal. Gov. Code §§12651(a) and 12652(c)(1), from on or before January 1, 1988 to the present date.

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SECTION NO. 1 SUMMARY OF THE ACTION

- 1. This is an action for damages, treble damages, civil penalties and costs against the DEFENDANT PHARMACEUTICAL MANUFACTURERS arising from :
- A. the DEFENDANT PHARMACEUTICAL MANUFACTURERS repeatedly and knowingly: causing the making and using of grossly inflated, false price and cost records and statements regarding certain pharmaceutical products specified herein to get false claims paid or approved by the State of California Medicaid Program; causing to be presented to an officer or employee of the State of California false claims for payment or approval regarding certain pharmaceutical products specified herein, and;
- B. the DEFENDANT PHARMACEUTICAL MANUFACTURERS repeatedly and knowingly providing discounts, rebates, free pharmaceuticals, grants and other forms of remuneration that were in most cases not reflected, reported or disclosed on the invoices to their customers which caused: the providers' true purchase prices to be obfuscated: the State of California to approve and pay providers' Medicaid claims in amounts that grossly exceeded the reasonable amounts permitted by law; the creation of excessive illegal profits for the providers; and overutilization by the providers of the pharmaceuticals of the DEFENDANT PHARMACEUTICAL MANUFACTURERS.

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- 2. The specified pharmaceuticals are ordinarily sold by the DEFENDANT PHARMACEUTICAL MANUFACTURERS directly or through wholesalers to physicians or outpatient clinics, such as oncology group physician practices, and to specialty infusion pharmacies, such as the Qui Tam Plaintiff, which then provide the drugs and biologicals and related supplies directly to the patient intravenously, by injection or inhalation. These infusion, injectable and inhalation drugs and biologicals are primarily used to treat the most seriously ill patients who are afflicted with cancer, Acquired Immune Deficiency Syndrome ("AIDS"), severe infections, respiratory diseases and immune deficiency diseases.
- and used by the Defendants in a manner to cause the State of California Medicaid Program to rely upon them in paying claims for the pharmaceuticals specified herein sold by the DEFENDANT PHARMACEUTICAL MANUFACTURERS. As a direct and proximate result of the use of the false price and cost records and statements and the use of the undisclosed discounts and other forms of illegal remuneration provided by the DEFENDANT PHARMACEUTICAL MANUFACTURERS, the State of California's Medicaid Program was caused to pay and approve claims for the pharmaceuticals specified herein of the DEFENDANT PHARMACEUTICAL MANUFACTURERS in amounts that grossly and materially exceeded the reasonable payment amount for such pharmaceuticals permitted by the applicable federal and state law. The claims for payment in grossly excessive amounts were false claims because they were based on

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false and fraudulent price and cost records and statements made by the DEFENDANT PHARMACEUTICAL MANUFACTURERS and because they were for amounts that exceeded the reasonable amount permitted to be paid under applicable law. The claims were fraudulent claims because they were paid in such excessive amounts only because of the falsely inflated price and cost records and statements knowingly made and used by the DEFENDANT PHARMACEUTICAL MANUFACTURERS. The Defendants thus caused the presentation of false claims for payment and approval to officers or employees of the State. Additionally, the Defendants' false reports of price and cost information constituted false statements and/or records that were made and used for the purpose of getting false claims approved or paid by the State.

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- 6. By falsely representing their price and cost information, the DEFENDANT PHARMACEUTICAL MANUFACTURERS induced the State to pay exorbitant and unreasonable sums of money to the customers of the DEFENDANT PHARMACEUTICAL MANUFACTURERS to which they were not entitled and which induced them to utilize more of the specified drugs to obtain greater excessive profits.
- 7. The DEFENDANT PHARMACEUTICAL MANUFACTURERS' customers participated in the false claims scheme by filing and/or presenting claims for the specified pharmaceuticals in grossly excessive amounts without disclosing that the amounts were excessive or the existence of deep discounts, rebates and other forms of financial remuneration paid directly or indirectly to induce the customers to utilize the DEFENDANT PHARMACEUTICAL MANUFACTURERS' specified pharmaceutical products. Certain of the customers furthered the fraud scheme by using the exorbitant "reimbursement" amounts received in payment for claims presented to the State of

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California to fund additional illegal financial inducements paid to referring and/or prescribing physicians of the specified pharmaceuticals for California Medicaid beneficiaries.

8. The DEFENDANT PHARMACEUTICAL MANUFACTURERS knew or should have known that their false representations of prices and costs would cause the State Medicaid program to pay grossly excessive and unreasonable amounts of money for claims for their pharmaceutical products and that said payments would, in significant part, be made by the State. DEFENDANT PHARMACEUTICAL MANUFACTURERS have caused the State since on or before January 1, 1988 to date to sustain damages as a result of the false representations of prices and costs knowingly made by them.

Accordingly, the State is entitled to recover treble damages, plus civil penalties and costs from the DEFENDANT PHARMACEUTICAL MANUFACTURERS in excess of ONE HUNDRED MILLION AND 00/100 DOLLARS (\$100,000,000.00) pursuant to Cal. Gov. Code §\$12651(a)(1) and (2) and 12652(c)(1), et. seq.

SECTION No. 2

THE PARTIES

9. The Plaintiff in this action is the State of California. At all times material to this civil action, the California Department of Health and Human Services, the Department of Health Services and Medi-Cal were agencies and instrumentalities of the State and their activities, operations and contracts in administering the Medicaid program were paid from State's funds. The State and its subcontractors performing on

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behalf of the State provided Medicaid benefits to qualified recipients which included payment of claims for the pharmaceuticals specified herein manufactured by the DEFENDANT PHARMACEUTICAL MANUFACTURERS and relied upon the false price and cost representations made by the DEFENDANT PHARMACEUTICAL MANUFACTURERS in approving and paying claims.

10. The Qui Tam Plaintiff, VEN-A-CARE, is a corporation organized under the laws of the State of Florida, with its principal offices in Key West, Florida. The Qui Tam Plaintiff's principal officers and directors include Zachary T. Bentley and T. Mark Jones, who are each citizens of the United States and reside in Key West, Florida. The Qui Tam Plaintiff is an infusion pharmacy and provides pharmaceuticals, such as the intravenous, injectable or inhalation drugs and biologicals specified in this Complaint as a Florida Medicaid provider and as a Medicare Part B supplier. The Qui Tam Plaintiff has direct and independent knowledge of the information and is the "original source" of the information on which these allegations are based within the meaning of Cal. Gov. Code §12652(d)(3)(A) and (B). The Qui Tam Plaintiff has standing to bring this action pursuant to Cal. Gov. Code §12652(c)(1). The information upon which these allegations are based was voluntarily provided by the Qui Tam Plaintiff to the State and has been frequently supplemented by the Qui Tam Plaintiff. A portion of the original source information provided by the Qui Tam Plaintiff consists of truthful price and cost information for the specified pharmaceuticals which is available to the Qui Tam Plaintiff as an industry insider, albeit a very small one. Ven-A-Care's cost information provided

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herein is, therefore, very conservative and the truthful cost and price information for the
specified pharmaceuticals to California Medicaid providers is equal to or less than that
alleged herein as the actual cost to Ven-A-Care because those California providers have
arger businesses than Ven-A-Care and can command greater volume purchasing
reduction in prices.
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20. The Defendant, DEY LABORATORIES ("DEY"), is a corporation organized
under the laws of Delaware with its principal offices in Napa, California. At all times
material to this civil action, DEY has transacted business in the State of California by,
including but not limited to, selling and distributing the specified pharmaceutical product
to purchasers within the State of California including San Diego County.
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34. The Defendants specified in paragraphs 11 through 33 are sometimes referred to herein collectively as the "DEFENDANT PHARMACEUTICAL MANUFACTURERS". Any and all acts alleged herein to have been committed by any or all of the DEFENDANT PHARMACEUTICAL MANUFACTURERS were committed by said Defendant's officers, directors, employees, or agents who at all times acted on behalf of their respective DEFENDANT DRUG MANUFACTURER.

SECTION NO. 3

JURISDICTION & VENUE

- 35. Jurisdiction is founded upon the State of California False Claims Act, (the "Act") Cal. Gov. Code §§12651(a) and 12652(c)(1) et. seq. The purpose of the Act is intended to deter persons from knowingly causing or assisting in causing State government to pay claims that are false and to provide remedies for civil penalties of up to \$10,000.00 for each false claim plus three (3) times the amount of damages which the State sustains when money is obtained from State government by reason of a false claim, Cal. Gov. Code §§12651(a) and 12652(c)(1).
- 36. The Act reaches the type of false claims activity alleged herein in accordance with the express language of the Act as well as precedents arising from applications of the substantially similar Federal False Claims Act. Specifically, the United States Supreme Court's application of the Federal False Claims Act in <u>United States v. Neifert-White Company</u>, 390 U.S. 228; 88 S.Ct. 959 (1968) found:

- A. "... the Act was intended to reach all types of fraud, without qualification, that might result in financial loss to the Government." 88 S.Ct., at 961.
- B. The Act applies to the conduct of a Defendant manufacturer that supplies falsely inflated price information in support of a customer's claim. 88 S.Ct., at 960.
- C. The Act applies even where the price information supplied by the Defendant manufacturer is inflated by only approximately 25% over the truthful price. 88 S.Ct., at 960.
- D. The Act applies even though the Defendant did not submit the false price information directly and received no direct payment off funds. The Act applies even though the inflated portion of the price was received by customers of the Defendant who are not parties to the case. 88 S.Ct., at 960.
- 37. Venue in the Superior Court of San Diego County, California is appropriate and sufficient contacts for jurisdiction exist in that each of the DEFENDANTS transacted business in the State of California by selling directly or through others their specified pharmaceutical products in the State of California including San Diego County which the respective DEFENDANTS knew would be supplied to Medi-Cal recipients including those residing in San Diego County and for which the DEFENDANTS knew that grossly excessive and unreasonable payments for claims would be made to the providers/suppliers by the Medi-Cal program.

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- 38. A copy of this Complaint and written disclosure of substantially all material evidence and information VEN-A-CARE possesses were served on the State pursuant to Cal. Gov. Code §12652(c)(3) on the same day as this Complaint was filed <u>in camera</u> and under seal by service via registered mail, return receipt requested on the Attorney General in Sacramento, California.
- 39. The Qui Tam Plaintiff alleges: (A) that no allegation or transaction of defrauding the State was made prior to the filing of the Complaint in public disclosures regarding the subject matter herein against any of the DEFENDANTS; (B) that none of the DEFENDANTS was named in public disclosures made prior to the filing of the Complaint regarding the subject matter herein; and (C), if the Court makes a finding against the Qui Tam Plaintiff as to the allegations set forth in (A) and/or (B), the Qui Tam Plaintiff is the original source of the information and has direct and independent knowledge of the information on which these allegations are based within the meaning of Cal. Gov. Code §12652(d)(3)(A) and (B) and has voluntarily provided the information to the State before filing the Complaint which is based on the information provided by the Qui Tam Plaintiff to the State.

SECTION NO. 4

SYNOPSIS OF THE FALSE CLAIM SCHEME

4(A) BACKGROUND

40. In the United States, prescription drugs and biologicals are only provided or dispensed to patients upon the order of a physician.

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- 41. Prescription drugs provided outside of the hospital setting are sold ordinarily by community retail pharmacies (i.e. Longs, Saveon, Rite Aid and neighborhood independent drug stores) directly to the patient. Typically a patient is provided a prescription for a particular drug by a physician. The patient takes the prescription and independently selects the pharmacy at which the prescription will be filled. Thus, the prescribing physician has no financial incentive or financial inducement to prescribe a particular drug or recommend a specific drug as the therapy of choice over that of a possible alternative therapy.
- 42. This case, however, focuses on a different and distinct type of pharmaceuticals which cannot be taken by mouth and cannot be self administered. The specified pharmaceuticals are generally administered to the patient by a professional (i.e. a nurse) intravenously, by injection or inhalation. Many of the specified pharmaceuticals are commonly referred to as "chemotherapy", "chemo" or "oncology" drugs. The other drugs at issue include, but are not limited to, those drugs which are used in conjunction with chemotherapy and intravenous IV antibiotics, IV antiviral and IV antifungals. The biologicals at issue include but are not limited to those which are used to treat a variety of immune deficiency disorders. A biological product is one which has been obtained directly from, or has been derived from, living matters. The above described types of drugs and biologicals are collectively hereinafter sometimes referred to as "infusion, injectable or inhalation pharmaceuticals" and the particular

pharmaceuticals at issue in this case are sometimes referred to as "the specified pharmaceuticals."

- 43. The specified pharmaceuticals at issue in this Complaint are generally not available for sale at community retail pharmacies. In most cases, the specified pharmaceuticals are only available through a hospital (either inpatient or outpatient), a specialized physician or clinic operated by a group of physicians or a specialized pharmacy.
- 44. Specialized pharmacies such as the Qui Tam Plaintiff's are sometimes known as home infusion pharmacies, IV pharmacies or home IV pharmacies. Throughout the United States, it is very common to have physicians financially associated directly or indirectly with specialized pharmacies. This association may be through an ownership interest, service as consultant or medical director, or other financial relationships. The Qui Tam Plaintiff's pharmacy has three physician investors, none of which owns more than 5%.
- 45. The DEFENDANT PHARMACEUTICAL MANUFACTURERS refer to these specialized pharmacies as "closed Pharmacies" or by a similar descriptive name which generally means the pharmacies are not open to the public.
- 46. The specified pharmaceuticals are ordinarily prescribed by specialized physicians for the treatment of people who are afflicted with various forms of cancer, AIDS and HIV diseases.

- 47. Physicians who specialize in the treatment of cancers and their associated blood disorders are known as oncologists and hematologists. Physicians who specialize in the treatment of AIDS and HIV diseases are known as Infectious Disease or "ID" physicians.
- 48. The specialized physicians are in a unique relationship with the DEFENDANT PHARMACEUTICAL MANUFACTURERS for the specified pharmaceuticals in this Complaint in that the physicians not only prescribe the specified pharmaceuticals, but also directly provide and administer or arrange for provision and administration of the specified pharmaceuticals.
- 49. The DEFENDANT PHARMACEUTICAL MANUFACTURERS have each acted to induce physicians to order the pharmaceuticals at issue in this case by falsely representing inflated price and cost information such as direct prices, wholesale acquisition costs, published prices and average wholesale prices so that claims submitted to the State Medicaid Program for these drugs will be paid to the physicians or specialized pharmacies in amounts that grossly exceed the reasonable amount permitted by law.

4(B) SPECIFIC FACT PATTERNS

- 50. The false claim scheme of the DEFENDANT PHARMACEUTICAL MANUFACTURERS is typically implemented in the following ways:
- A. A pharmaceutical manufacturer possesses a patented or formerly patented pharmaceutical and the manufacturer desires to induce physicians to utilize the

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manufacturer's pharmaceutical for their patients. The pharmaceutical manufacturer will knowingly reduce its true prices for the pharmaceuticals but will make false representations of inflated cost and price information upon which California Medicaid claims will be approved and paid. The physician ordering the pharmaceutical and submitting the claim will thus receive substantially more money for the pharmaceutical than a reasonable amount and will thus be induced financially to order it for his or her patients.

- B. Generic versions of a pharmaceutical become available and compete with the "brand name" manufacturer that held the patent on the pharmaceutical. The generic manufacturers sell the pharmaceutical to physicians, clinics and specialty pharmacies at prices far below the price level reported by the brand manufacturer but make false representations of their pharmaceuticals' prices. Often, the false prices reported by the generic manufacturers exceed the already inflated price reported by the brand name manufacturer. As a result, physicians, who must decide whether to order a particular pharmaceutical, and their clinics and specialty pharmacies receive payments from the California Medicaid Program for claims for infusion and injectable pharmaceuticals that far exceed their cost.
- C. Manufacturers of brand and generic drugs and biologicals report false and fraudulent price and cost information to the California Medicaid Program and cause providers to receive unreasonably high payments for claims so that providers are

induced to prescribe or administer the manufacturer's pharmaceutical rather than an alternative pharmaceutical or non-pharmaceutical therapy.

4(C) SURROUNDING CIRCUMSTANCES

- 51. The false claim scheme perpetrated by the DEFENDANT

 PHARMACEUTICAL MANUFACTURERS is aided by circumstances which include, but are not limited to the following:
- A. The infusion and injectable cancer chemotherapy and AIDS therapy pharmaceuticals at issue in this case are generally perceived to be high priced and often are high priced during the time they are subject to a patent held by the brand name manufacturer.
- B. Consumers are unable to price shop for the pharmaceuticals at issue in this case as they do with pharmaceuticals purchased at community retail pharmacies.
- C. The price and cost representations made by pharmaceutical manufacturers, in general, including the DEFENDANT PHARMACEUTICAL MANUFACTURERS, for many other pharmaceuticals bear a truthful relationship to their true prices and costs and the State of California thus routinely relies on these representations.
- D. Patients who receive the specified pharmaceuticals are extremely ill and not in a position to question their physician's decision as to who will provide the

specified pharmaceuticals, which manufacturer's pharmaceuticals to use or as to the amount claimed for providing the specified pharmaceuticals.

- E. The patients and third party payers, including the California Medicaid Program, are not aware of the prices actually paid for the specified pharmaceuticals by the physician, clinic or specialty pharmacy which presented the claim for payment. The DEFENDANT PHARMACEUTICAL MANUFACTURERS conceal from the State's Medicaid Program price reductions occurring due to competition in the marketplace and falsely and fraudulently represent pharmaceutical prices that far exceed the truthful prices.
- F. The California Medicaid Program is required to pay claims for the specified pharmaceuticals by estimating the wholesale acquisition cost to the provider and relies on the price and cost representations made by the manufacturer in determining the payment amount for the specific manufacturer's pharmaceuticals.
- G. Physicians, clinics and specialty pharmacies submitting claims to the State Medicaid Program for the pharmaceuticals at issue in this case are paid for their professional services which are separately reimbursable charges. The State's Medicaid Program is prohibited by law from paying and never intended to pay the grossly excessive amounts for the specified pharmaceuticals. Those providers or referrers of the specified pharmaceuticals in a position to increase utilization of the specified pharmaceuticals thus receive exorbitant sums of money in excess of the

reasonable amounts provided by law, all due to the false price and cost representations made by the DEFENDANT PHARMACEUTICAL MANUFACTURERS.

52. The DEFENDANT PHARMACEUTICAL MANUFACTURERS each occupy positions of privilege and trust in the United States because they develop new pharmaceutical products and produce life saving pharmaceuticals. In return, the Pharmaceutical Manufacturers benefit from patents on new pharmaceutical products that can be sold at prices, set by the manufacturers, that enable the manufacturers to enjoy huge profits above costs as an accepted inducement to develop the new pharmaceutical products. When patents expire and other manufacturers bring "generic" versions of the formerly patented pharmaceutical to the market, prices ordinarily fall due to competition and due to the fact that the generic manufacturers did not expend the large sums of money on research and development as did the original brand manufacturers. Prices also fall when manufacturers compete against alternative therapies. Manufacturers also reduce prices so that third party payers will cover their pharmaceutical for payment. Due to the Qui Tam Plaintiff's position in the industry, the Qui Tam Plaintiff has been made privy to the truthful cost and price information that has been concealed from the California Medicaid Program and have directly witnessed the methods employed by each of the DEFENDANT PHARMACEUTICAL MANUFACTURERS in carrying out the false and fraudulent claims schemes set out herein. The Qui Tam Plaintiff has further witnessed that the California Medicaid Program incurred damages because the DEFENDANT PHARMACEUTICAL

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MANUFACTURERS concealed price reductions and caused the illusion that the
specified pharmaceuticals continued to be sold at the price levels commanded by brand
manufacturers before the price reductions occurred resulting from competition.
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4(D) AN EFFECT OF FALSE PRICING SCHEME AND RESULTING ILLEGAL SPLIT FEE ARRANGEMENTS IS TO DRIVE LAW ABIDING COMPETITORS OUT OF BUSINESS

The actions of the DEFENDANT PHARMACEUTICAL MANUFACTURERS 54. alleged herein result in grossly excessive amounts being paid to their customers by the California Medicaid Program for claims submitted for the specified pharmaceuticals. Accordingly, the exorbitant payments induce physicians, clinics and specialty pharmacies to increase the utilization of the specified pharmaceuticals. The DEFENDANT PHARMACEUTICAL MANUFACTURERS were in a position to increase the utilization of their specified pharmaceuticals by causing an enormous concealed financial inducement to be unwittingly paid by the California Medicaid Program to the DEFENDANT PHARMACEUTICAL MANUFACTURERS' customers, the physicians and specialized pharmacies. The financial inducement was so great for many of the specified pharmaceuticals at issue in this Complaint that the profits derived from the provision of the specified pharmaceuticals greatly exceeded the physicians' professional fees and provided what can only be characterized as "windfall profits." markets, including the Qui Tam Plaintiff's, specialty pharmacies and clinics are unable to compete unless they enter financial arrangements with prescribing physicians whereby the grossly excessive amounts paid by the State's Medicaid Program are split with the prescribing physicians. Over the last six (6) years, the Qui Tam Plaintiff's business has all but been extinguished because of the Qui Tam Plaintiff's refusal to participate in the

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false claims schemes specified herein. The Qui Tam Plaintiff has been unable to effectively compete with those physicians as well as clinics and specialty pharmacies who participate in the DEFENDANT PHARMACEUTICAL MANUFACTURERS' false claims scheme paying illegal financial inducements to the prescribing physicians.

- 4(E) FALSE PRICING SCHEME "THE SPREAD"

 Direct Benefits to Pharmaceutical Manufacturers Maximizing Sales Volume, Capturing Market Share
 and Increasing Utilization of Products
- directly from their false pricing scheme of concealing their true prices while making grossly inflated false and fraudulent representations of prices and costs by maximizing their products' sales volume, capturing market share for their products, and increasing utilization of their products by providers. An example of how the DEFENDANT PHARMACEUTICAL MANUFACTURERS directly benefit from their false pricing scheme is demonstrated by data for the first quarter of 1997 from the State of Florida's Medicaid Program setting out Florida's Medicaid reimbursements paid to the customers of pharmaceutical manufacturers and utilization of their products by their customers for the drug
- 56. Albuterol is a pharmaceutical which is administered by inhalation and is used for the treatment of many respiratory illnesses. Albuterol provides an example of how two (2) pharmaceutical manufacturers, DEFENDANTS and DEY, maximized sales volume and captured the Florida Medicaid pharmacy market for

Albuterol to the detriment of Florida's Medicaid Program. The methods used to capture Medicaid Pharmacy business is typical of those employed by the DEFENDANT PHARMACEUTICAL MANUFACTURERS in other states, including California. Pharmaceutical manufacturers capture market share and maximize their sales volume by concealing their true prices while falsely and fraudulently representing grossly inflated prices which creates a spread between the providers' costs and the amount of reimbursement from a state's Medicaid Program. The Qui Tam Plaintiff's evidence demonstrates that providers will purchase and utilize the pharmaceutical manufacturer's product that has the widest spread between the provider's true cost and the reimbursement paid by third parties including the States' Medicaid Programs and Medicare. First quarter, 1997 reimbursement data from the State of Florida's Medicaid Program demonstrates that the wider the spread between the true cost paid by providers versus the reimbursement paid by Medicaid the more a specific manufacturer's product will be utilized instead of a competitor's product. The DEY and the DEFENDANT PHARMACEUTICAL MANUFACTURERS pharmaceutical manufacturers . have all made representations of Wholesale Acquisition Cost to the State of Florida as set out in the chart below. As a result of the false representations of prices and costs, the DEFENDANT PHARMACEUTICAL MANUFACTURERS DEY caused the State of Florida's Medicaid Program unwittingly to pay more than one million dollars for the first quarter of 1997 over the reasonable reimbursement amounts which the State

of Florida intended to pay. The chart further sets out the number of reimbursed claims, VEN-A-CARE's cost per ml and "the spread" between Medicaid reimbursement and true cost.

FALSE PRICING SCHEME - "THE SPREAD" FLORIDA MEDICAID REIMBURSEMENT (1st Quarter 1997)

Ma	nufacturer	VAC's Cost per ml	Florida Medicaid Reimbursement per ml	The Spread	# of claims	Reimbursement paid by Florida Medicaid
	TOTAL REIMBURSEMENT BY THE STATE OF FLORIDA \$1,477,075.86 MEDICAID PROGRAM (January 1 through March 31, 1997)					\$1,477,075.86
**	** The use of the spread to falsify claims is evidenced by the fact that and customers will receive a greater windfall by purchasing and product than the customers could if the customers somehow acquired the same product from or free of charge.					

57. The grossly inflated payments unwittingly made by the State's Medicaid Program not only served as an inducement to providers to purchase a particular manufacturer's product but also served to drive over utilization. The Qui Tam Plaintiff, prior to filing the Complaint, surveyed three national pharmacy providers of determine their business practices for their sales of to the Medicare and States' Medicaid Programs. The Qui Tam Plaintiff's principals used positions in an

affiliated home health care company to pose as an interested customer. The Qui Tam Plaintiff determined that the payment of kickbacks and/or split fees were common place between the pharmacies and home health care companies who could provide the pharmacies with patient referrals. One marketing scheme offered by one of the pharmacies was the automatic shipping of refills of every month without verifying continuing need with the patient or physician in order to maximize the sales of and reimbursement.

58. For many of the specified pharmaceuticals, the DEFENDANT
PHARMACEUTICAL MANUFACTURERS' false and fraudulent representations of price and cost caused the Medicare Program to pay and approve claims at such excessive amounts that the 20% co-payment exceeded the true price of the pharmaceuticals. In the cases of Medicare beneficiaries who are additionally eligible for Medicaid benefits as the secondary payor, the State's Medicaid Program paid the excessive, inflated Medicare 20% co-payment. The chart below lists some of those specified pharmaceuticals, the amount approved in 1996 by California Medicare, the 20% co-payment and the true price paid by the Qui Tam Plaintiff.

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- 59. Through the above described scheme of concealing their true prices and representing falsely inflated prices and costs, the DEFENDANT PHARMACEUTICAL MANUFACTURERS caused the State's Medicaid Program to pay kickbacks (illegal remuneration) from Federal and State funds to the DEFENDANT PHARMACEUTICAL MANUFACTURERS' customers.
- 60. In many instances, the kickbacks paid from State and Federal funds were in excess of 1,000% over the providers' true costs and over the reasonable reimbursement amounts which the State intended to pay. The grossly excessive profits have led to a proliferation of illegal split fee arrangements between the pharmaceutical manufacturers' customers and persons or entities who are in a position to refer patients.

The split fee/kickbacks also serve as a financial inducement for the referrals of more patients and greater utilization of the products.

61. This case focuses on the specified pharmaceuticals manufactured by and/or distributed by the DEFENDANT PHARMACEUTICAL MANUFACTURERS and sold either directly, through wholesalers or through group purchasing organizations to physicians, such as oncologists, hematologists and infectious disease physicians and others as well as the specialized "closed" pharmacies.

SECTION NO. 5

BACKGROUND OF HOW PHARMACEUTICAL CLAIMS ARE PAID FOR UNDER THE STATE OF CALIFORNIA'S MEDICAID PROGRAM

- 62. The United States Government partially funds state sponsored medical assistance programs for the poor pursuant to Title XIX of the Social Security Act, 42 U.S.C. §1396 et seg.
- 63. Benefits for pharmaceuticals are optional but all states have opted to provide Medicaid pharmaceutical reimbursement coverage.
- 64. The federal portion of state Medicaid payments, Federal Medical Assistance Percentage ("FMAP") is based on a state's per capita income compared to the national average. The federal portion consists of a minimum of 50% up to a maximum of 83%. California's FMAP contributed by the United States in 1995 was 50.00%.

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- 65. The States, United States Territories and the District of Columbia are required to implement a State Health Plan containing certain specified minimum criteria for coverage and payment of claims in order to qualify for federal funds for Medicaid expenditures. 42 U.S.C. §1396a(a)(30)(A).
- 66. State Health Plans must, in part, provide for payment of claims for prescription pharmaceuticals pursuant to a formula approved by the Secretary of the Department of Health and Human Services which determines maximum allowable claim amount for each pharmaceutical manufactured by each manufacturer whose prescription pharmaceuticals qualify for Medicaid reimbursement based upon an estimation of the provider's acquisition cost plus a reasonable dispensing fee. 42 CFR 447.331.
- 67. In order to comply with the requirements of 42 CFR 447.331 to estimate a provider's costs for specific pharmaceuticals, the States' Medicaid programs acquire and receive price and cost information from the DEFENDANT PHARMACEUTICAL MANUFACTURERS directly and indirectly from entities equipped to do specialized data collection.
- 68. Medical Economics, Inc. and the Hearst Corporation are nationally recognized companies that specialize in gathering pharmaceutical pricing and cost information including Average Wholesale Price ("AWP"), Wholesale Acquisition Cost ("WAC"), Direct Price ("DP"), Actual Acquisition Cost ("AAC") and Estimated Acquisition Cost ("EAC"). Medical Economics publishes pharmaceutical pricing information in "The

Red Book". The Hearst Corporation publishes pharmaceutical pricing information through its First Data Bank Division, which is a automated data base service.

- 69. The Qui Tam Plaintiff's investigation has shown that during the time covered by this Complaint that:
- A. The California Medicaid program pays for pharmaceuticals under two programs:
 - (i) Pharmacy and;
 - (ii) Incident to a physician's service
- B. The State of California's reimbursement formula for a pharmaceutical is a multi-faceted determination of estimated acquisition cost set forth as follows: Estimated Acquisition Cost ("EAC") for . . . a drug product shall be:
- (i) The Direct Price as determined pursuant to Section 51513.5; or
- (ii) The Average Wholesale Price minus 5% (AWP 5%) for all other drug products.
- C. The California Code describes how Medi-Cal determines AWP as follows: Average Wholesale Price (AWP), excepting temporary updates provided in subdivision (a)(13), means the price for a drug product or medical supply product listed for a standard package in the Department's primary price reference source, or for products not listed in the Department's primary price reference source, the price listed for a standard package in the secondary price reference source; and, if not listed in the

secondary price source, the principal labeler's catalogue. The selection of the primary price reference source and the secondary price reference source shall be based upon an evaluation of the various price reference sources available in relation to the following criteria:

- (i) Accuracy and currentness of prices.
- (ii) Comprehensiveness of data base.
- (iii) Capability to meet the needs of the Department's fiscal intermediary.

The primary price reference source will be the price reference source that, in the judgment of the Director, best meets the criteria specified above. The secondary price reference source will be the price reference source that, in the judgment of the Director when evaluated against the criteria listed above, is inferior to the primary price reference source but superior to all others evaluated.

- D. The Estimated Acquisition Cost that is the Direct Price is determined pursuant to California Code Section 51513.5 as set out as follows:
- (i) The estimated acquisition cost for all of the drug products manufactured or distributed by a pharmaceutical company listed below shall be the direct price listed for a standard package in the Department's primary reference source; or for products not listed in the Department's primary price reference source, the direct price listed for a standard package in the secondary price reference source; or, if not listed in the secondary price source, the principal labeler's catalogue.

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(ii) Pharmaceutical Company List:

BILLING CODE	PHARMACEUTICAL COMPANY
AB	Abbot Laboratories
AY	Ayerst Laboratories
LE	Lederle Laboratories
MS	Merck, Sharpe and Dohme
PD	Parke Davis and Company
PF	Pfizer Laboratories
RR	Roerig, J.B. and Company
RS	Ross Laboratories
SQ	Squibb, E.R. and Sons
UP	Upjohn Company, The
WY	Wyeth Laboratories

E. The reasoning of the California Legislature for paying the eleven (11) manufacturers on their Direct Price rather than AWP minus 5% for all other pharmaceutical manufacturers was that the California Medicaid Program was aware that the vast majority of sales of these 11 manufacturers was on a direct sale basis from the manufacturer to the provider. California Medicaid reimbursement methodology of AWP minus 5% was intended to pay for a reasonable wholesaler's mark-up for the wholesaler services provided. Therefore, for the 11 manufacturers who sold directly to the providers, the State of California's Medicaid Program wanted to eliminate the

wholesalers' mark-ups to make sure that the State paid the lower true Direct Price when no wholesaler was used.

- F. The State of California's reimbursement for pharmaceuticals incident to a physician's services is based on a Level 3 HCPS Code from the Physician's Handbook which is unique to California Medicaid. California physicians are paid by how much of the pharmaceuticals are dispensed, i.e. 51 mg, instead of how much was purchased.
- G. The State of California's Medicaid pharmacy program has relied upon representations of AWP and Direct Price supplied by the Hearst Corporation's First Data Bank in setting reimbursement amounts for pharmaceuticals;
- H. The Hearst Corporation's First Data Bank relies solely upon the pricing information provided by the DEFENDANT PHARMACEUTICAL MANUFACTURERS for the drugs specified in this Complaint in establishing or reporting the DEFENDANT PHARMACEUTICAL MANUFACTURERS' AWPs and Direct Prices.
- Reimbursement for pharmaceuticals incident to a physician's service has been set by California Medicaid Pharmacy Services.
- 70. Pharmacy claims are submitted in one of two ways. The first is by submitting to the fiscal agent or state agency a completed (hard copy 30-1) pharmacy claim form. The second is through an electronic claims filing procedure whereby the same information required to be included on the hard copy is transmitted electronically to the Medicaid fiscal agent or state agency.

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- 71. Pharmacies must bill Medicaid by utilizing National Drug Codes ("NDC") numbers. The Food and Drug Administration ("FDA") assigns NDC numbers to identify each individual manufacturer and their pharmaceuticals' strength and size. NDC numbers are eleven digits, with the first five digits identifying the manufacturer or labeler, the next four digits identifying the product and the last two digits identifying the package size.
- 72. Claims for pharmaceuticals incident to a physician service are submitted in one of two ways. The first is by submitting to the fiscal agent or state agency a completed (hard copy) HCFA 1500 claim form. The second is through an electronic claims filing procedure whereby the same information required to be included on the hard copy is transmitted electronically to the Medicaid fiscal agent or State Agency.
- 73. Physicians must bill Medicaid for pharmaceuticals by utilizing an 5-digit alpha numeric system created by the State of California and referred to as a HCPCS Level 3. By way of example, the 5-digit code for submitting claims for the drug.

 In addition to being reimbursed for the cost of the pharmaceutical, physicians receive a payment of \$3.93 to cover the cost of the needle, syringe and alcohol swab.
- 74. The State of California awards cost-reimbursement contracts to private companies to evaluate and process Medicaid recipients' claims for payment. The State refers to these contractors as fiscal agents.

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75. This case focuses on the specified pharmaceuticals that are covered under the California Medicaid Program which are sold and/or distributed by the DEFENDANT PHARMACEUTICAL MANUFACTURERS and for which the California Medicaid Program relied on the false cost and price representations reported by the DEFENDANT PHARMACEUTICAL MANUFACTURERS to pay and approve claims.

SECTION NO. 6

THE DEFENDANT PHARMACEUTICAL MANUFACTURERS' KNOWLEDGE OF THE FALSE CLAIMS SCHEME

- 76. At all times material to this action, each of the DEFENDANT PHARMACEUTICAL MANUFACTURERS acted "knowingly" as that term is defined in Cal. Gov. Code §§12650(b)(2) by:
- A. Causing the presentation of false claims for payment or approval by the State's Medicaid Program; and
- B. Causing the making and using of false statements and/or records for the purpose of getting false claims approved or paid by the State's Medicaid Program.
- 77. The DEFENDANT PHARMACEUTICAL MANUFACTURERS were clearly placed on notice that their conduct would cause the State's Medicaid program to pay claims for the specified pharmaceuticals in amounts exceeding that permitted by applicable law, in part, because:

- A. Each of the DEFENDANT PHARMACEUTICAL

 MANUFACTURERS was on notice of federal statutes and regulations limiting payment

 of Medicaid claims for the specified pharmaceuticals to an amount necessary to cover

 the cost of the pharmaceutical.
- B. Each of the DEFENDANT PHARMACEUTICAL

 MANUFACTURERS was on notice that the California Medicaid Program was not authorized or permitted by applicable law to pay claims for the specified pharmaceuticals in excessive amounts.
- C. Each of the DEFENDANT PHARMACEUTICAL

 MANUFACTURERS was on notice that federal and California statutes and regulations prohibited them from making misleading representations about the specified pharmaceuticals, including misleading price or cost representations:
- (i) Each of the DEFENDANT PHARMACEUTICAL

 MANUFACTURERS is required to comply with the Federal Food, Drug and Cosmetic

 Act 21 U.S.C. §321 et. seq., and the regulations promulgated pursuant thereto.
- (ii) The price and cost representations about the specified pharmaceuticals constitute advertising that is included in the "labeling" provisions of the Federal Food and Drug Act and related regulations. 21 U.S.C. §§201(m); 202.1(k)(2).
- (iii) Each of the DEFENDANT PHARMACEUTICAL

 MANUFACTURERS is prohibited from disseminating any information about their prices

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or costs of th	ne specified p	harmaceuticals that is "false or misleading in any particular
." 21 U.S.C.	§§5.02; 302(k	o).
	(iv)	Each of the DEFENDANT PHARMACEUTICAL
MANUFACT	URERS was	on notice that they possessed a duty to assure that their
representation	ons about pric	ces and costs of the specified pharmaceuticals were not
misleading, t	taking into acc	count:
	statement, v	y representations made or suggested by vord, design, device, or any combination thereof, ne extent to which the labeling or advertising fails that the such representations"
21 U.S.C. §2	201(n).	
78.	The DEFEN	DANT PHARMACEUTICAL MANUFACTURERS regularly
make direct	representatio	ns of false price and cost information to the State of
California's I	Medicaid ager	ncy that are relied upon in approving and paying claims.
79.	Another exa	mple of a pharmaceutical manufacturer making direct false
and fraudule	nt representa	tions of price and cost to a state Medicaid pharmacy program
is the non de	efendant,	(" ") that manufacturers the
drug,		is a drug recently introduced that is administered to resolve

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nausea in patients undergoing chemotherapy. When entered the market,
potential alternatives were
, both of which are the subject of false price representations
beginning before the entry of Section . It is manufactured in both tablet and
injectable form.
80. A State of Florida Pharmacy Program Official directly contacted
and informed its representative that Florida Medicaid needed accurate and truthful
wholesale price information about in order to verify the pricing information that
Florida had received through First Data Bank. In response to this request,
provided the written representations on December 17, 1997 that are attached as Exhibit
"6". made AWP and Net Price representations about six different versions of
its oral and also about its one version of the injectable,
. California would ordinarily estimate wholesale acquisition cost (
"WAC") by adding 7% to representation of Net Price which in the instant case
lead to a reimbursement of \$133.62 for the 100 mg/5ml vial. While the Florida Official
was asking for truthful prices for so that reimbursement amounts
could be verified, the Qui Tam Plaintiff contacted representatives through its
". The Qui Tam Plaintiff made it very clear that it did not want to
receive any amount from Medicaid in excess of that which Florida Medicaid intended to
pay. The Qui Tam Plaintiff requested that the representative calculate the
proper Florida Medicaid reimbursement amount for injectable

the Qui Tam Plaintiff received, on December 18, 1997, what is attached as **Exhibit "7".**On the cover page, the representative of the "grant and applying WAC reimbursement for the grant injectable using a price of \$70.00 and applying WAC plus 7%. The Florida Medicaid reimbursement was thus calculated by representatives to be \$74.90. **Exhibit "8"** is a price list for through its distributor grant and lists the truthful prices for available to the Qui Tam Plaintiff. A wholesale cost of \$70.00 is specified as the price for the injectable in orders of as little as one unit.

Applying truthful prices to Florida's WAC methodology results in a maximum reimbursement of \$74.90 for one unit of the 100 mg/5ml vial of injectable **Exhibit "9"**, represented that its true Net Price is \$124.90. When the WAC plus 7% formula is applied, a reimbursement of \$133.64 results which is 78% greater than the amount that even admits would result from reliance upon truthful prices.

Exhibits "8" and "9" also contain price representations for the oral versions of

A comparison of those representations and the resulting reimbursement

amounts with the injectable reveals that Florida's reimbursement methodology works

when it is supplied with truthful prices. The following Charts illustrate the impact of false

price representations on the State of Florida Medicaid Pharmacy Program:

The following charts illustrate that reimbursement amounts are set at the State of Florida's and the State of California's intended reasonable levels when the manufacturer tells the truth for the oral or tablet form of the drug and at unintended excessive levels when the manufacturer lies about the injectable form of the drug:

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As the example illustrates, the State's Medicaid Program continues to receive false price representations from manufacturers of certain infusion, injectable and inhalation drugs that mislead reimbursement officials into paying excessive amounts to the Manufacturer's customers, physicians and specialty pharmacies.

- 81. The DEFENDANT PHARMACEUTICAL MANUFACTURERS were each fully capable of making truthful representations about prices and costs of the specified pharmaceuticals and do so when it is economically beneficial to them.
- 82. The DEFENDANT PHARMACEUTICAL MANUFACTURERS each participated in the Medicaid rebate program mandated by the Omnibus Budget Reconciliation Act of 1990 ("OBRA '90") and thus were required to pay rebates to the State Medicaid program based upon their average manufacturer's price ("AMP") for non-innovator multi-source pharmaceuticals (generics) or best price ("BP") single source innovator drugs (Brand) for the specified pharmaceuticals at issue in this case. The

AMP rebate amount is currently 11% and the BP is currently a minimum of 17% or more based on a formula between the drug manufacturers' difference in AMP and BP. The method of calculating rebates, therefore, causes it to be in the economic interests of the DEFENDANT PHARMACEUTICAL MANUFACTURERS to report the lowest AMPs and Best Prices based on the data available to them.

The following examples demonstrate that the DEFENDANT DRUG
MANUFACTURES are able to report accurate prices when they choose to:

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B.			

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Medicaid program for the pharmaceuticals at issue in this case, the DEFENDANT PHARMACEUTICAL MANUFACTURERS falsely reported amounts far in excess of those reported for OBRA '90 rebate purposes. Therefore, when it benefitted the DEFENDANT PHARMACEUTICAL MANUFACTURERS to report highest prices to maximize the reimbursement amount for the select providers from the Medicare and Medicaid programs, they used the false and grossly inflated prices and, when it benefitted the DEFENDANT PHARMACEUTICAL MANUFACTURERS to report their true prices to minimize the rebates they were required to pay the State's Medicaid

Program, they used the true prices driven low by competition. Accordingly, the DEFENDANT PHARMACEUTICAL MANUFACTURERS knowingly reported false inflated price and cost information, in part, because each DEFENDANT DRUG MANUFACTURER's participation in the rebate program demonstrates its ability to report accurate prices, yet each DEFENDANT DRUG MANUFACTURER knowingly failed to use that ability when it knew its price and cost reports were being relied upon in paying and approving Medicaid claims.

changes a representation of its drug cost or price can be dramatic regardless of whether a State's reimbursement methodology estimates a provider's actual acquisition cost pursuant to federal regulation 42 CFR 447.331 as AWP minus a percentage or WAC plus a percentage. The representations made by the DEFENDANT PHARMACEUTICAL MANUFACTURERS regarding their direct prices to First Data Bank, Medical Economics and directly to the States' Medicaid Programs are material for the establishment of reasonable reimbursements by the States' Medicaid Programs. The importance that Pharmaceutical Manufacturers represent truthful direct prices and how the representations of direct prices affect reimbursements in States whose formula is WAC plus a percentage and States whose formula is AWP minus a percentage is demonstrated by the following example:

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- 85. Each DEFENDANT DRUG MANUFACTURER was on notice that it was prohibited by federal statute, from paying, or causing the payment of, directly or indirectly, money or other financial benefit to induce its customers to order the specified pharmaceuticals when the California Medicaid Program would be paying claims. 42 U.S.C. §1320a-7b(b)(2).
 - 86. Notwithstanding the above statutory requirements and prohibitions:

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repeatedly, systematically and falsely represented to the Medicare and California Medicaid Programs that the prices of certain of the generic versions of the specified drugs were the same or higher than the published price for the equivalent brand drug when they knew that, in truth and in fact, the price of their generic drug was far less than the published price of the brand and that the State's Medicaid Program would pay and approve claims based upon their representations of the false price of their drugs.

THE MEDI-CAL PROGRAM DUPED INTO PAYING AS MUCH OR MORE FOR GENERIC DRUGS THAN THEIR EQUIVALENT BRAND

COMPANY	SIZE	NDC#	MEDI-CAL	QUI TAM PLAINTIFF'S COST

COMPANY	SIZE	NDC#	MEDI-CAL	QUI TAM PLAINTIFF'S COST

COMPANY	SIZE	NDC #	MEDI-CAL	QUI TAM PLAINTIFF'S COST

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COMPANY	SIZE	NDC #	MEDI-CAL	QUI TAM PLAINTIFF'S COST

COMPANY	SIZE	NDC#	MEDI-CAL	QUI TAM PLAINTIFF'S COST

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COMPANY	SIZE	NDC#	MEDI-CAL	QUI TAM PLAINTIFF'S COST

COMPANY	SIZE	NDC #	MEDI-CAL	QUI TAM PLAINTIFF'S COST

COMPANY	SIZE	NDC #	MEDI-CAL	QUI TAM PLAINTIFF'S COST

COMPANY	SIZE	NDC #	MEDI-CAL	QUI TAM PLAINTIFF'S COST

COMPANY	SIZE	NDC #	MEDI-CAL	QUI TAM PLAINTIFF'S COST

COMPANY	SIZE	NDC #	MEDI-CAL	QUI TAM PLAINTIFF'S COST

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87.	Delei	ndants

represented to the California Medicaid Program that the prices of certain of their specified pharmaceuticals were increasing or remaining constant when they knew that in truth and in fact the prices had fallen substantially and the California Medicaid Program would pay and approve claims based on their representations of the false price of their

pharmaceuticals.

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SECTION NO. 7

FINANCIAL INDUCEMENT

- 88. The financial inducement to those in a position to increase the utilization of the Defendants' pharmaceuticals is illustrated by the following examples of common drug therapies for certain of the specified drugs:
- A. Patient "A" is diagnosed with Metastatic Gastric Carcinoma and prescribed a combination chemotherapy regimen to be given on three consecutive days every twenty-one to twenty-eight days for ten (10) cycles. The prescription for this therapy is:

Calculation of E	<u> ach Drug's Do</u>	<u>sage</u> :	
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COMPARISONS OF QUI TAM PLAINTIFF'S COST VS. MEDICARE ALLOWABLE AND MEDICAID REIMBURSEMENT FOR ONE (1) CYCLE:					
Qui Tam Plaintiff's COST vs California MEDICAID					
\$184.78 \$2,981.88					

COMPARISONS OF QUI TAM PLAINTIFF'S COST VS. MEDICAID REIMBURSEMENT FOR TEN (10) CYCLES:				
Qui Tam Plaintiff's COST vs California MEDICAID				
\$1,847.80 \$29,818.80				

The above example is of a chemotherapy regimen obtained from Handbook of Commonly Used Chemotherapy Regimens, F. Anthony Greco, M.D., Precept Press, 1996. It does not include any professional or dispensing fees, supportive drugs or intravenous fluids prescribed which are all separately reimbursable by Medicare and the State's Medicaid Program.

	B.	Patient "B" is dia	ignosed with Cold	on Cancer and is	s prescribed a
chemothera	apy regir	nen of	and	once a week fo	or six (6) cycles
The prescri	ption for	this therapy is:			
Calc	ulation	of Each Drug's	Dosage Is:		

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		\$1,079.18

COMPARISONS OF QUI TAM PLAINTIFF'S COST VS. MEDICAID REIMBURSEMENT FOR ONE (1) CYCLE:				
Qui Tam Plaintiff's COST vs California MEDICAID				
\$40.17 \$1,079.18				

COMPARISONS OF QUI TAM PLAINTIFF'S COST VS. MEDICAID REIMBURSEMENT FOR SIX (6) CYCLES (6 WEEKS):				
Qui Tam Plaintiff's COST vs California MEDICAID				
\$241.02 \$6,475.08				

The above example is of a chemotherapy regimen obtained from <u>Journal of Clinical Oncology</u>, 5: 1559-1565, 1987. It does not include any professional or

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dispensing fees, supportive drugs or intravenous fluids prescribed which are all
separately reimbursable by Medicare and State's Medicaid Program.
C. Patient "C" is diagnosed with Small Cell Lung Cancer and is
prescribed a chemotherapy regimen consisting of and and for five (5)
days every twenty-one (21) days for four (4) cycles. The prescription for this therapy is:
Calculation of Each Drug's Dosage:

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COMPARISONS OF QUI TAM PLAINTIFF'S COST VS. MEDICAID REIMBURSEMENT FOR ONE (1) CYCLE:				
Qui Tam Plaintiff's COST	Qui Tam Plaintiff's COST vs			
\$680.68	\$1,670.12			

COMPARISONS OF QUI TAM PLAINTIFF'S COST VS. MEDICAID REIMBURSEMENT FOR FOUR (4) CYCLES:				
Qui Tam Plaintiff's COST	vs	California MEDICAID		
\$2,722.72		\$6,680.48		

The above example is of a chemotherapy regimen obtained from <u>Handbook of Commonly Used Chemotherapy Regimens</u>, F. Anthony Greco, M.D., Precept Press, 1996. It does not include any professional or dispensing fees, supportive drugs or intravenous fluids prescribed which are all separately reimbursable by Medicare and State's Medicaid Program.

89. The knowledge of the DEFENDANT PHARMACEUTICAL

MANUFACTURERS is further demonstrated by their systematic and ongoing, written
and verbal communications with customers whereby they encourage and induce them
to submit claims to Medicare and Medicaid to receive the excessive payments resulting
from the Defendants' false price and cost representations.

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Additionally DEFENDANTS and and	
each maintain an "800" number, staffed with personnel trained to assist customers in	
securing payment of claims in the excessive amounts at issue in this action.	
90. As an example of the DEFENDANT PHARMACEUTICAL	
MANUFACTURERS' use of their false and fraudulent practices to market their products	ı
follows:	
A.	
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B. In or about 1995, VEN-A-CARE began ordering from	
hrough their sales representative, (hereinafter referred to as """).	
also gave VEN-A-CARE prices for other manufacturers'	
hen began purchasing () since the purchase price for was	>
\$5.00 to \$6.00 less per gram.	

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	C.	When r	ealized that VE	N-A-CARE was no lo	onger
purchasing		but using	she called	T. Mark Jones on Ma	arch 20, 1996 at
9:40 A.M. D	uring thi	s phone convers	ation,	informed Jones that	she was
concerned w	ith VEN	-A-CARE's purcl	nasing	instead of	
She stated t	hat, eve	n though VEN-A-	CARE could sa	ave a few dollars on t	he initial
acquisition c	ost of	, VEN-A-0	CARE would no	ot benefit from the am	ount of
reimburseme	ent relat	ed to	greater AWP.	She stated that	AWP in
the 1996 Re	d Book	was \$290.00 for	5 grams and		AWP in 1996

91. An example of the DEFENDANT PHARMACEUTICAL MANUFACTURERS' admission that their price and cost representations are false follows:

VEN-A-CARE to make \$50.00 more per 5 gram purchases. stated that VEN-

A-CARE needed to compare AWP to other manufacturers when purchasing

was \$340.00 for 5 grams. She stated that the larger spread from

for Medicaid patients since has the largest spread.

- A. On or about December 3, 1996, VEN-A-CARE's Bentley and Jones were contacted by a Florida Medicaid Pharmacy Official. The Official requested Bentley's and Jones' assistance in providing the State of Florida with truthful prices for the drug, Immune Globulin Intravenous (Human) ("IVIG").
- B. The Official remembered that Bentley had inquired of the Official a couple of years prior (in 1994) concerning the utilization of IVIG in the Florida Medicaid

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Pharmacy Program. Bentley informed the Official that the true prices being paid for IVIG by providers were significantly less than the Florida Medicaid Program's reimbursement, Bentley informed the Official that VEN-A-CARE's current cost was approximately \$25.00 per gram. Bentley also informed the Official that the grossly excessive reimbursement by Florida's Medicaid Pharmacy Program was a concealed financial inducement for providers to increase the utilization of IVIG and pay illegal kickbacks to the prescribing physician. In response to Bentley's request, the Official provided Bentley with data for the utilization and expenditures of IVIG in the Florida Medicaid Pharmacy Program for the second quarter of 1994. The data indicated approximately 1.1 Million Dollars in utilization.

- C. Since 1994, the utilization and cost to the Medicaid Program of IVIG has increased dramatically and has become a significant expenditure for the Florida Medicaid Pharmacy Program, approaching approximately 20 Million Dollars annually.
- D. In response to the dramatic increase in utilization of IVIG, the State of Florida Medicaid official examined Florida's pricing reimbursement and upon review, the Official lowered Florida's reimbursement from approximately \$80.00 per gram to approximately \$37.00 per gram.
- E. After the reduction of the IVIG reimbursement amount by Florida Medicaid, some, if not all, of the DEFENDANT PHARMACEUTICAL

MANUFACTURERS producing IVIG contacted the Official in an effort to reinstate the prior IVIG reimbursement prices.

- F. Florida requested VEN-A-CARE to provide copies of invoices, catalogues and any other pricing information on IVIG in order to substantiate Florida's reimbursement position for IVIG.
- G. The State of Florida Medicaid representatives used the information provided by Ven-A-Care in their discussions with certain of the DEFENDANT PHARMACEUTICAL MANUFACTURERS, and, as a result, the manufacturers retreated from their contentions that Florida should continue to pay exorbitant amounts for claims for IVIG and adjusted their price representations.
- 92. The damages sought herein include, but are not limited to, those arising from the specific pharmaceuticals set out in Sections 8 through 28 and elsewhere throughout this Complaint. The specific pharmaceuticals set out herein are alleged to meet the specificity required in pleading the claims alleged as required by law. The damages sought herein encompass all damages and penalties arising from the false claims relating to all pharmaceuticals of all sizes of the DEFENDANT PHARMACEUTICAL MANUFACTURERS about which false price and cost representations and records caused the presentment of false claims for payment and approval. These claims also encompass recovery of the funds paid due to the false claims, regardless of the person or entity that ultimately received the funds.

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SECTION NO. 8	
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- 95. The acts of Defendant in knowingly providing false and misleading price information to the California Medicaid Program:
- A. Were committed knowingly in order to cause California Medicaid's

 Program to pay amounts for claims for the specified pharmaceuticals that substantially

 exceeded the amounts that would otherwise would have been paid according to law.
- B. Were committed knowingly in order to cause California's Medicaid

 Program to pay unwittingly excessive amounts for the Defendant's pharmaceuticals.
- C. Were committed knowingly in order to induce financially the Defendant's customers, and those acting in concert with them, to cause the Defendant's specified pharmaceuticals to be utilized for the treatment of Medicaid recipients.

- D. Were committed knowingly in order to induce financially the Defendant's customers and those acting in concert with them to select the Defendant's pharmaceutical products for Medicaid recipients rather than select similar pharmaceuticals of competitors, or prescribe alternative therapies.
- E. Did in fact cause the Defendant's customers, and those acting in concert with them, to utilize the Defendant's specified pharmaceuticals for treatment of Medicaid recipients rather than competing pharmaceuticals or alternative therapies.

SECTION NO. 9

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- 98. The acts of Defendant in knowingly providing false and misleading price information to the California Medicaid Program:
- A. Were committed knowingly in order to cause California Medicaid's

 Program to pay amounts for claims for the specified pharmaceuticals that substantially exceeded the amounts that would otherwise would have been paid according to law.
- B. Were committed knowingly in order to cause California's Medicaid

 Program to pay unwittingly excessive amounts for the Defendant's pharmaceuticals.
- C. Were committed knowingly in order to induce financially the Defendant's customers, and those acting in concert with them, to cause the Defendant's specified pharmaceuticals to be utilized for the treatment of Medicaid recipients.
- D. Were committed knowingly in order to induce financially the Defendant's customers and those acting in concert with them to select the Defendant's pharmaceutical products for Medicaid recipients rather than select similar pharmaceuticals of competitors, or prescribe alternative therapies.
- E. Did in fact cause the Defendant's customers, and those acting in concert with them, to utilize the Defendant's specified pharmaceuticals for treatment of Medicaid recipients rather than competing pharmaceuticals or alternative therapies.



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101. The acts of Defendant in knowingly providing false and misleading price information to the California Medicaid Program:

- A. Were committed knowingly in order to cause California Medicaid's

 Program to pay amounts for claims for the specified pharmaceuticals that substantially

 exceeded the amounts that would otherwise would have been paid according to law.
- B. Were committed knowingly in order to cause California's Medicaid

 Program to unwittingly pay excessive amounts for the Defendant's pharmaceuticals.
- C. Were committed knowingly in order to induce financially the Defendant's customers, and those acting in concert with them, to cause the Defendant's specified pharmaceuticals to be utilized for the treatment of Medicaid recipients.
- D. Were committed knowingly in order to induce financially the Defendant's customers, and those acting in concert with them, to select the Defendant's pharmaceutical products for Medicaid recipients rather than select similar pharmaceuticals of competitors, or prescribe alternative therapies.
- E. Did in fact cause the Defendant's customers, and those acting in concert with them, to utilize the Defendant's specified pharmaceuticals for treatment of Medicaid recipients rather than competing pharmaceuticals or alternative therapies.

SECTION NO: 11

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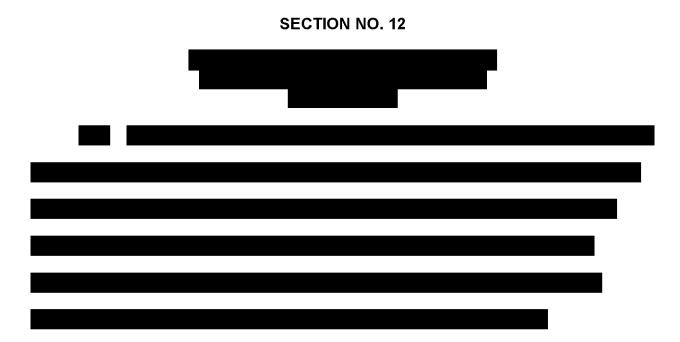
104. The acts of Defendant in knowingly providing false and misleading price information to the California Medicaid Program:

A. Were committed knowingly in order to cause California Medicaid's

Program to pay amounts for claims for the specified pharmaceuticals that substantially
exceeded the amounts that would otherwise would have been paid according to law.

- B. Were committed knowingly in order to cause California's Medicaid

 Program to unwittingly pay excessive amounts for the Defendant's pharmaceuticals.
- C. Were committed knowingly in order to induce financially the Defendant's customers, and those acting in concert with them, to cause the Defendant's specified pharmaceuticals to be utilized for the treatment of Medicaid recipients.
- D. Were committed knowingly in order to induce financially the Defendant's customers, and those acting in concert with them, to select the Defendant's pharmaceutical products for Medicaid recipients rather than select similar pharmaceuticals of competitors, or prescribe alternative therapies.
- E. Did in fact cause the Defendant's customers, and those acting in concert with them, to utilize the Defendant's specified pharmaceuticals for treatment of Medicaid recipients rather than competing pharmaceuticals or alternative therapies.



CASE NO:	
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- 107. The acts of Defendant in knowingly providing false and misleading price information to the California Medicaid Program:
- A. Were committed knowingly in order to cause California Medicaid's

 Program to pay amounts for claims for the specified pharmaceuticals that substantially exceeded the amounts that would otherwise would have been paid according to law.
- B. Were committed knowingly in order to cause California's Medicaid

 Program to unwittingly pay excessive amounts for the Defendant's pharmaceuticals.
- C. Were committed knowingly in order to induce financially the Defendant's customers, and those acting in concert with them, to cause the Defendant's specified pharmaceuticals to be utilized for the treatment of Medicaid recipients.
- D. Were committed knowingly in order to induce financially the Defendant's customers, and those acting in concert with them, to select the Defendant's drug products for Medicaid recipients rather than select similar drugs of competitors, or prescribe alternative therapies.

CASE NO:	
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E. Did in fact cause the Defendant's customers, and those acting in concert with them, to utilize the Defendant's specified pharmaceuticals for treatment of Medicaid recipients rather than competing drugs or alternative therapies.

SECTION NO. 13

CASE NO:

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- 110. The acts of Defendant in knowingly providing false and misleading price information to the California Medicaid Program:
- A. Were committed knowingly in order to cause California Medicaid's

 Program to pay amounts for claims for the specified pharmaceuticals that substantially exceeded the amounts that would otherwise would have been paid according to law.
- B. Were committed knowingly in order to cause California's Medicaid

 Program to unwittingly pay excessive amounts for the Defendant's pharmaceuticals.
- C. Were committed knowingly in order to induce financially the Defendant's customers, and those acting in concert with them, to cause the Defendant's specified pharmaceuticals to be utilized for the treatment of Medicaid recipients.
- D. Were committed knowingly in order to induce financially the Defendant's customers, and those acting in concert with them, to select the Defendant's pharmaceutical products for Medicaid recipients rather than select similar drugs of competitors, or prescribe alternative therapies.

E. Did in fact cause the Defendant's customers, and those acting in concert with them, to utilize the Defendant's specified pharmaceuticals for treatment of Medicaid recipients rather than competing drugs or alternative therapies.

SECTION NO. 14

CASE NO:
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- 113. The acts of Defendant in knowingly providing false and misleading price information to the California Medicaid Program:
- A. Were committed knowingly in order to cause California Medicaid's

 Program to pay amounts for claims for the specified pharmaceuticals that substantially

 exceeded the amounts that would otherwise would have been paid according to law.
- B. Were committed knowingly in order to cause California's Medicaid

 Program to unwittingly pay excessive amounts for the Defendant's pharmaceuticals.

- C. Were committed knowingly in order to financially induce the Defendant's customers, and those acting in concert with them, to cause the Defendant's specified pharmaceuticals to be utilized for the treatment of Medicaid recipients.
- D. Were committed knowingly in order to financially induce the Defendant's customers, and those acting in concert with them, to select the Defendant's pharmaceutical products for Medicaid recipients rather than select similar drugs of competitors, or prescribe alternative therapies.
- E. Did in fact cause the Defendant's customers, and those acting in concert with them, to utilize the Defendant's specified pharmaceuticals for treatment of Medicaid recipients rather than competing drugs or alternative therapies.

SECTION NO. 15

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- 116. The acts of Defendant in knowingly providing false and misleading price information to the California Medicaid Program:
- A. Were committed knowingly in order to cause California Medicaid's

 Program to pay amounts for claims for the specified pharmaceuticals that substantially

 exceeded the amounts that would otherwise would have been paid according to law.
- B. Were committed knowingly in order to cause California's Medicaid

 Program to unwittingly pay excessive amounts for the Defendant's pharmaceuticals.
- C. Were committed knowingly in order to financially induce the Defendant's customers, and those acting in concert with them, to cause the Defendant's specified pharmaceuticals to be utilized for the treatment of Medicaid recipients.
- D. Were committed knowingly in order to financially induce the Defendant's customers, and those acting in concert with them, to select the Defendant's pharmaceutical products for Medicaid recipients rather than select similar drugs of competitors, or prescribe alternative therapies.
- E. Did in fact cause the Defendant's customers, and those acting in concert with them, to utilize the Defendant's specified pharmaceuticals for treatment of Medicaid recipients rather than competing drugs or alternative therapies.

SECTION NO. 16

THE SPECIFIC FALSE PRICE AND COST REPRESENTATIONS OF DEFENDANT DEY LABORATORIES

- 117. At various times from on or before January 1, 1988 and continuing through the present date, Defendant DEY LABORATORIES knowingly caused the State of California's Medicaid Program to pay false claims for drugs specified in this Section No. 16 and further made or used false records and/or statements to get such claims paid or approved. As a result of the said actions of Defendant DEY LABORATORIES and those persons and entities acting directly or indirectly in concert with Defendant DEY LABORATORIES, the State of California's Medicaid Program paid grossly excessive, unreasonable and unlawful amounts for claims for the drugs specified in this Section 16. The acts committed by Defendant DEY LABORATORIES that caused the State's Medicaid Program to pay or approve said false claims included, but were not necessarily limited to, knowingly making false representations about prices and costs of the drugs specified in this Section 16 which Defendant DEY LABORATORIES knew or should have known would be relied upon by the State's Medicaid Program in paying or approving claims for the drugs specified in this Section 16. Each of said representations were material and were relied upon by the State's Medicaid Program in paying or approving claims for the drugs specified in this Section 16.
- 118. Defendant DEY LABORATORIES knowingly caused its false price and cost representations to be published in the years specified in this Complaint by First Data Bank's Automated Services and Medical Economic's Red Book and further made or used false records or statements regarding its prices and costs of the drugs specified in this Section 16 and submitted same to the State's Medicaid Program continuously

throughout the years specified in this Section 16. For the purposes of specificity and particularity, the said false price and cost representations as they were submitted to First Data Bank in 1996 have been organized into a chart form for each drug by name, NDC number, California Medicaid payment Qui Tam Plaintiff's cost, the gross profit and the gross profit expressed as a percentage. The amount listed under the Qui Tam Plaintiff's cost columns reflects the true price that Defendant DEY LABORATORIES charged the Qui Tam Plaintiff for the drug or caused another entity to charge the Qui Tam Plaintiff for the drug. As a very small infusion pharmacy, the Qui Tam Plaintiff does not always receive the lowest prices available to volume purchasers. Accordingly, a comparison of the Qui Tam Plaintiff's costs with the price and cost representations made by the Defendant DEY LABORATORIES establishes the falsity of DEY LABORATORIES's representations for the drugs and years specified as follows:

DEFENDANT DEY					
Drug	NDC#	MEDI-CAL PAYMENT	Qui Tam Plaintiff's COST	PROVIDER'S GROSS PROFIT \$	PROVIDER'S GROSS PROFIT %
Albuterol Sulfate 0.083% 3 ml, 25s	49502-0697-03	\$28.74	\$8.50	\$20.25	238%
Albuterol Sulfate 0.083% 3 ml, 30s	49502-0697-33	\$34.49	\$10.20	\$24.29	238%
Albuterol Sulfate 0.083%, 3 ml 60s	49502-0697-60	\$68.98	\$20.40	\$48.58	238%

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DEFENDANT DEY					
Drug	NDC#	MEDI-CAL PAYMENT	Qui Tam Plaintiff's COST	PROVIDER'S GROSS PROFIT \$	PROVIDER'S GROSS PROFIT %
Acetylcysteine Solution 10% 30 ml	49502-0181-30	\$34.99	\$19.65	\$15.34	78%
Acetylcysteine Solution 20% 10 ml	49502-0182-10	\$15.41	\$9.90	\$5.51	55%
Acetylcysteine Solution 20% 30 ml	49502-0182-30	\$42.25	\$24.63	\$17.62	71%
Acetylcysteine Solution 20% 100 ml	49502-0182-00	\$154.09	\$24.50	\$129.59	528%
Cromolyn Sodium 2 ml 60s	49502-0689-02	\$39.90	\$24.50	\$15.40	62%
Cromolyn Sodium 2 ml 120s	49502-0689-12	\$79.80	\$49.00	\$30.80	62%
Metaproterenol Sulfate 0.4%	49502-0678-03	\$24.34	\$6.25	\$18.09	289%
Metaproterenol Sulfate 0.6% 2.5 ml 25 s	49502-0676-03	\$24.34	\$6.25	\$18.09	289%
Sodium Chloride 0.9% 15 ml	49502-0830-15	\$13.39	\$5.02	\$8.37	166%
Sodium Chloride 3% 15 ml 50s	49502-0640-15	\$48.45	\$27.50	\$20.95	76%

DEFENDANT DEY					
Drug	NDC#	MEDI-CAL PAYMENT	Qui Tam Plaintiff's COST	PROVIDER'S GROSS PROFIT \$	PROVIDER'S GROSS PROFIT %
Sodium Chloride 10% 15 ml 50s	49502-0641-15	\$48.45	\$27.50	\$20.95	76%

- 119. The acts of Defendant DEY in knowingly providing false and misleading price information to the California Medicaid Program:
- A. Were committed knowingly in order to cause California Medicaid's

 Program to pay amounts for claims for the specified pharmaceuticals that substantially

 exceeded the amounts that would otherwise would have been paid according to law.
- B. Were committed knowingly in order to cause California's Medicaid

 Program to unwittingly pay excessive amounts for the Defendant's pharmaceuticals.
- C. Were committed knowingly in order to financially induce the Defendant's customers, and those acting in concert with them, to cause the Defendant's specified pharmaceuticals to be utilized for the treatment of Medicaid recipients.
- D. Were committed knowingly in order to financially induce the Defendant's customers, and those acting in concert with them, to select the Defendant's pharmaceutical products for Medicaid recipients rather than select similar drugs of competitors, or prescribe alternative therapies.

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SECTION NO. 17

CASE NO:
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- 122. The acts of Defendant in knowingly providing false and misleading price information to the California Medicaid Program:
- A. Were committed knowingly in order to cause California Medicaid's

 Program to pay amounts for claims for the specified pharmaceuticals that substantially exceeded the amounts that would otherwise would have been paid according to law.
- B. Were committed knowingly in order to cause California's Medicaid

 Program to unwittingly pay excessive amounts for the Defendant's pharmaceuticals.
- C. Were committed knowingly in order to financially induce the Defendant's customers, and those acting in concert with them, to cause the Defendant's specified pharmaceuticals to be utilized for the treatment of Medicaid recipients.
- D. Were committed knowingly in order to financially induce the Defendant's customers, and those acting in concert with them, to select the Defendant's

pharmaceutical products for Medicaid recipients rather than select similar drugs of competitors, or prescribe alternative therapies.

SECTION NO. 18

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125. The acts of Defendant in knowingly providing false and misleading price information to the California Medicaid Program:

A. Were committed knowingly in order to cause California Medicaid's

Program to pay amounts for claims for the specified pharmaceuticals that substantially

exceeded the amounts that would otherwise would have been paid according to law.

- B. Were committed knowingly in order to cause California's Medicaid

 Program to unwittingly pay excessive amounts for the Defendant's pharmaceuticals.
- C. Were committed knowingly in order to financially induce the Defendant's customers, and those acting in concert with them, to cause the Defendant's specified pharmaceuticals to be utilized for the treatment of Medicaid recipients.
- D. Were committed knowingly in order to financially induce the Defendant's customers, and those acting in concert with them, to select the Defendant's pharmaceutical products for Medicaid recipients rather than select similar drugs of competitors, or prescribe alternative therapies.
- E. Did in fact cause the Defendant's customers, and those acting in concert with them, to utilize the Defendant's specified pharmaceuticals for treatment of Medicaid recipients rather than competing drugs or alternative therapies.

CASE NO:

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- 128. The acts of Defendant in knowingly providing false and misleading price information to the California Medicaid Program:
- A. Were committed knowingly in order to cause California Medicaid's

 Program to pay amounts for claims for the specified pharmaceuticals that substantially

 exceeded the amounts that would otherwise would have been paid according to law.
- B. Were committed knowingly in order to cause California's Medicaid

 Program to unwittingly pay excessive amounts for the Defendant's pharmaceuticals.
- C. Were committed knowingly in order to financially induce the Defendant's customers, and those acting in concert with them, to cause the Defendant's specified pharmaceuticals to be utilized for the treatment of Medicaid recipients.
- D. Were committed knowingly in order to financially induce the Defendant's customers, and those acting in concert with them, to select the Defendant's pharmaceutical products for Medicaid recipients rather than select similar drugs of competitors, or prescribe alternative therapies.

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- 131. The acts of Defendant in knowingly providing false and misleading price information to the California Medicaid Program:
- A. Were committed knowingly in order to cause California Medicaid's

 Program to pay amounts for claims for the specified pharmaceuticals that substantially

 exceeded the amounts that would otherwise would have been paid according to law.
- B. Were committed knowingly in order to cause California's Medicaid

 Program to unwittingly pay excessive amounts for the Defendant's pharmaceuticals.
- C. Were committed knowingly in order to financially induce the Defendant's customers, and those acting in concert with them, to cause the Defendant's specified pharmaceuticals to be utilized for the treatment of Medicaid recipients.
- D. Were committed knowingly in order to financially induce the Defendant's customers, and those acting in concert with them, to select the Defendant's pharmaceutical products for Medicaid recipients rather than select similar drugs of competitors, or prescribe alternative therapies.

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SECTION NO. 21

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- 134. The acts of Defendant in knowingly providing false and misleading price information to the California Medicaid Program:
- A. Were committed knowingly in order to cause California Medicaid's

 Program to pay amounts for claims for the specified pharmaceuticals that substantially exceeded the amounts that would otherwise would have been paid according to law.
- B. Were committed knowingly in order to cause California's Medicaid

 Program to unwittingly pay excessive amounts for the Defendant's pharmaceuticals.

- C. Were committed knowingly in order to financially induce the Defendant's customers, and those acting in concert with them, to cause the Defendant's specified pharmaceuticals to be utilized for the treatment of Medicaid recipients.
- D. Were committed knowingly in order to financially induce the Defendant's customers, and those acting in concert with them, to select the Defendant's pharmaceutical products for Medicaid recipients rather than select similar drugs of competitors, or prescribe alternative therapies.
- E. Did in fact cause the Defendant's customers, and those acting in concert with them, to utilize the Defendant's specified pharmaceuticals for treatment of Medicaid recipients rather than competing drugs or alternative therapies.

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- 137. The acts of Defendant in knowingly providing false and misleading price information to the California Medicaid Program:
- A. Were committed knowingly in order to cause California Medicaid's

 Program to pay amounts for claims for the specified pharmaceuticals that substantially exceeded the amounts that would otherwise would have been paid according to law.
- B. Were committed knowingly in order to cause California's Medicaid

 Program to unwittingly pay excessive amounts for the Defendant's pharmaceuticals.
- C. Were committed knowingly in order to financially induce the Defendant's customers, and those acting in concert with them, to cause the Defendant's specified pharmaceuticals to be utilized for the treatment of Medicaid recipients.
- D. Were committed knowingly in order to financially induce the Defendant's customers, and those acting in concert with them, to select the Defendant's pharmaceutical products for Medicaid recipients rather than select similar drugs of competitors, or prescribe alternative therapies.

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SECTION NO. 23

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- 140. The acts of Defendant in knowingly providing false and misleading price information to the California Medicaid Program:
- A. Were committed knowingly in order to cause California Medicaid's

 Program to pay amounts for claims for the specified pharmaceuticals that substantially exceeded the amounts that would otherwise would have been paid according to law.
- B. Were committed knowingly in order to cause California's Medicaid

 Program to unwittingly pay excessive amounts for the Defendant's pharmaceuticals.
- C. Were committed knowingly in order to financially induce the Defendant's customers, and those acting in concert with them, to cause the Defendant's specified pharmaceuticals to be utilized for the treatment of Medicaid recipients.

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- D. Were committed knowingly in order to financially induce the Defendant's customers, and those acting in concert with them, to select the Defendant's pharmaceutical products for Medicaid recipients rather than select similar drugs of competitors, or prescribe alternative therapies.
- E. Did in fact cause the Defendant's customers, and those acting in concert with them, to utilize the Defendant's specified pharmaceuticals for treatment of Medicaid recipients rather than competing drugs or alternative therapies.

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CASE NO:				

143. The acts of Defendant in knowingly providing false and misleading price information to the California Medicaid Program:

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- A. Were committed knowingly in order to cause California Medicaid's

 Program to pay amounts for claims for the specified pharmaceuticals that substantially

 exceeded the amounts that would otherwise would have been paid according to law.
- B. Were committed knowingly in order to cause California's Medicaid

 Program to unwittingly pay excessive amounts for the Defendant's pharmaceuticals.
- C. Were committed knowingly in order to financially induce the Defendant's customers, and those acting in concert with them, to cause the Defendant's specified pharmaceuticals to be utilized for the treatment of Medicaid recipients.
- D. Were committed knowingly in order to financially induce the Defendant's customers, and those acting in concert with them, to select the Defendant's pharmaceutical products for Medicaid recipients rather than select similar drugs of competitors, or prescribe alternative therapies.
- E. Did in fact cause the Defendant's customers, and those acting in concert with them, to utilize the Defendant's specified pharmaceuticals for treatment of Medicaid recipients rather than competing drugs or alternative therapies.

SECTION NO. 25

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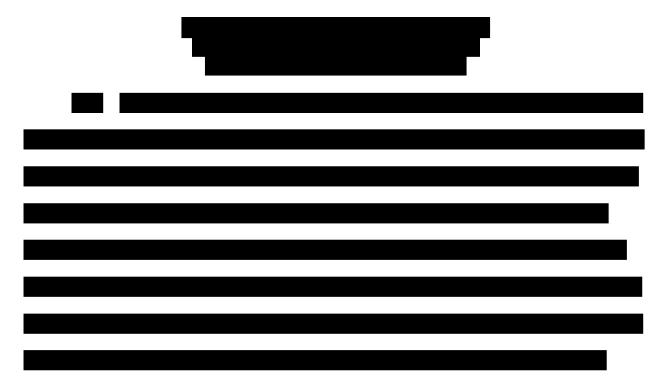
146. The acts of Defendant in knowingly providing false and misleading price information to the California Medicaid Program:

- A. Were committed knowingly in order to cause California Medicaid's

 Program to pay amounts for claims for the specified pharmaceuticals that substantially exceeded the amounts that would otherwise would have been paid according to law.
- B. Were committed knowingly in order to cause California's Medicaid

 Program to unwittingly pay excessive amounts for the Defendant's pharmaceuticals.

- C. Were committed knowingly in order to financially induce the Defendant's customers, and those acting in concert with them, to cause the Defendant's specified pharmaceuticals to be utilized for the treatment of Medicaid recipients.
- D. Were committed knowingly in order to financially induce the Defendant's customers, and those acting in concert with them, to select the Defendant's pharmaceutical products for Medicaid recipients rather than select similar drugs of competitors, or prescribe alternative therapies.
- E. Did in fact cause the Defendant's customers, and those acting in concert with them, to utilize the Defendant's specified pharmaceuticals for treatment of Medicaid recipients rather than competing drugs or alternative therapies.



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- 149. The acts of Defendant in knowingly providing false and misleading price information to the California Medicaid Program:
- A. Were committed knowingly in order to cause California Medicaid's

 Program to pay amounts for claims for the specified pharmaceuticals that substantially exceeded the amounts that would otherwise would have been paid according to law.
- B. Were committed knowingly in order to cause California's Medicaid

 Program to unwittingly pay excessive amounts for the Defendant's pharmaceuticals.
- C. Were committed knowingly in order to financially induce the Defendant's customers, and those acting in concert with them, to cause the Defendant's specified pharmaceuticals to be utilized for the treatment of Medicaid recipients.
- D. Were committed knowingly in order to financially induce the Defendant's customers, and those acting in concert with them, to select the Defendant's

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pharmaceutical products for Medicaid recipients rather than select similar drugs of competitors, or prescribe alternative therapies.

SECTION NO. 27



CASE NO:

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- 152. The acts of Defendant in knowingly providing false and misleading price information to the California Medicaid Program:
- A. Were committed knowingly in order to cause California Medicaid's Program to pay amounts for claims for the specified pharmaceuticals that substantially exceeded the amounts that would otherwise would have been paid according to law.
- B. Were committed knowingly in order to cause California's Medicaid Program to unwittingly pay excessive amounts for the Defendant's pharmaceuticals.
- C. Were committed knowingly in order to financially induce the Defendant's customers, and those acting in concert with them, to cause the Defendant's specified pharmaceuticals to be utilized for the treatment of Medicaid recipients.
- D. Were committed knowingly in order to financially induce the Defendant's customers, and those acting in concert with them, to select the Defendant's pharmaceutical products for Medicaid recipients rather than select similar drugs of competitors, or prescribe alternative therapies.
- E. Did in fact cause the Defendant's customers, and those acting in concert with them, to utilize the Defendant's specified pharmaceuticals for treatment of Medicaid recipients rather than competing drugs or alternative therapies.

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SECTION NO. 28	
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- 155. The acts of Defendant in knowingly providing false and misleading price information to the California Medicaid Program:
- A. Were committed knowingly in order to cause California Medicaid's Program to pay amounts for claims for the specified pharmaceuticals that substantially exceeded the amounts that would otherwise would have been paid according to law.
- B. Were committed knowingly in order to cause California's Medicaid Program to unwittingly pay excessive amounts for the Defendant's pharmaceuticals.
- C. Were committed knowingly in order to financially induce the Defendant's customers, and those acting in concert with them, to cause the Defendant's specified pharmaceuticals to be utilized for the treatment of Medicaid recipients.
- D. Were committed knowingly in order to financially induce the Defendant's customers, and those acting in concert with them, to select the Defendant's pharmaceutical products for Medicaid recipients rather than select similar drugs of competitors, or prescribe alternative therapies.

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E. Did in fact cause the Defendant's customers, and those acting in concert with them, to utilize the Defendant's specified pharmaceuticals for treatment of Medicaid recipients rather than competing drugs or alternative therapies.

COUNT I

CALIFORNIA FALSE CLAIMS ACT; CAUSING PRESENTATION OF FALSE CLAIMS

1:	56.	This is a civil action by the Plaintiff, THE STATE OF CALIFORNIA, and the	е
Qui Tam	ı Plai	intiff, VEN-A-CARE, on behalf of THE STATE OF CALIFORNIA, against the	е
Defenda	ınts,		
		DEY LABORATORIES;	

under the California False Claims Act, Cal. Gov. Code §§12651(a)(1) and 12652(c)(1) et. seq.

- 157. Qui Tam Plaintiff realleges and incorporates by reference paragraphs 1 through 155 as if fully set forth herein and further alleges as follows:
- 158. The DEFENDANT PHARMACEUTICAL MANUFACTURERS from a date on or before January 1, 1988 to the present date, knowingly [as defined in Cal. Gov. Code §§12650(b)(2)] caused to be presented to officers or employees of THE STATE OF CALIFORNIA false claims for payment or approval, in that the DEFENDANT PHARMACEUTICAL MANUFACTURERS caused to be presented to officers or employees of THE STATE OF CALIFORNIA false price and cost information for the pharmaceuticals specified herein and caused THE STATE OF CALIFORNIA to pay out sums of money to the providers and suppliers of the DEFENDANT PHARMACEUTICAL MANUFACTURERS' specified pharmaceuticals, grossly in excess of the amounts permitted by law, resulting in great financial loss to THE STATE OF CALIFORNIA.
- 159. Because of the DEFENDANT PHARMACEUTICAL MANUFACTURERS' conduct as set forth in this Count, THE STATE OF CALIFORNIA suffered actual damages in excess of One Hundred Million Dollars (\$100,000,000.00), all in violation of Cal. Gov. Code §12651(a)(1).

CASE NO:	
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COUNT II

CALIFORNIA FALSE CLAIMS ACT; CAUSING A FALSE RECORD OR STATEMENT TO BE MADE OR USED TO GET A FALSE CLAIM PAID OR APPROVED BY THE STATE OF CALIFORNIA

160. This is a civil action by the Plaintiff, THE STATE OF CALIFORNIA	, and the
Qui Tam Plaintiff, VEN-A-CARE, on behalf of THE STATE OF CALIFORNIA, ag	jainst the
Defendants,	
DEY LABORATORIES;	
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under the California False Claims Act, Cal. Gov. Code §§12651(a)(2) and 126	52(c)(1)
<u>et</u> . <u>seq</u> .	

161. Qui Tam Plaintiff realleges and incorporates by reference paragraphs 1 through 155 as if fully set forth herein and further alleges as follows:

CASE NO:

- 162. The DEFENDANT PHARMACEUTICAL MANUFACTURERS, from a date on or before January 1, 1988 to the present date, knowingly [as defined in Cal. Gov. Code §12650(b)(2)] caused false records or statements to be made or used to get false claims to be paid or approved by THE STATE OF CALIFORNIA, in that the DEFENDANT PHARMACEUTICAL MANUFACTURERS, caused false records or statements of prices and costs of the DEFENDANT PHARMACEUTICAL MANUFACTURERS' pharmaceuticals specified herein to be used by THE STATE OF CALIFORNIA to pay or approve claims presented by the providers and suppliers of the DEFENDANT PHARMACEUTICAL MANUFACTURERS' specified pharmaceuticals, which claims were grossly in excess of the amounts permitted by law, resulting in great financial loss to THE STATE OF CALIFORNIA.
- 163. Because of the DEFENDANT PHARMACEUTICAL MANUFACTURERS' conduct as set forth in this Count, THE STATE OF CALIFORNIA suffered actual damages in excess of One Hundred Million Dollars (\$100,000,000.00), all in violation of Cal. Gov. Code §12651(a)(2).

COUNT III

CALIFORNIA FALSE CLAIMS ACT; CAUSING FALSE RECORDS OR STATEMENTS TO BE USED TO CONCEAL AN OBLIGATION TO PAY MONEY TO THE STATE OF CALIFORNIA

This is a civil action by the Plaintiff, THE STATE OF CALIFORNIA, and the Qui Tam Plaintiff, VEN-A-CARE, on behalf of THE STATE OF CALIFORNIA, against the Defendants,

DEY LABORATORIES; under the California False Claims Act, Cal. Gov. Code §§12651(a)(7) and 12652(c)(1) et. seq.	CASE NO:
under the California False Claims Act, Cal. Gov. Code §§12651(a)(7) and 12652(c)(1)	
under the California False Claims Act, Cal. Gov. Code §§12651(a)(7) and 12652(c)(1)	
under the California False Claims Act, Cal. Gov. Code §§12651(a)(7) and 12652(c)(1)	
under the California False Claims Act, Cal. Gov. Code §§12651(a)(7) and 12652(c)(1)	
under the California False Claims Act, Cal. Gov. Code §§12651(a)(7) and 12652(c)(1)	
under the California False Claims Act, Cal. Gov. Code §§12651(a)(7) and 12652(c)(1)	
under the California False Claims Act, Cal. Gov. Code §§12651(a)(7) and 12652(c)(1)	
under the California False Claims Act, Cal. Gov. Code §§12651(a)(7) and 12652(c)(1)	
under the California False Claims Act, Cal. Gov. Code §§12651(a)(7) and 12652(c)(1)	
	DEY LABORATORIES;
<u>et</u> . <u>seq</u> .	under the California False Claims Act, Cal. Gov. Code §§12651(a)(7) and 12652(c)(1)
	et. seq.

- 164. Qui Tam Plaintiff realleges and incorporates by reference paragraphs 1 through 155 as if fully set forth herein and further alleges as follows:
- 165. The DEFENDANT PHARMACEUTICAL MANUFACTURERS, from a date on or before January 1, 1988 to the present date, knowingly [as defined in Cal. Gov. Code §12650(b)(2)] caused false records or statements to be made or used to conceal obligations to pay money to THE STATE OF CALIFORNIA, in that: the DEFENDANT PHARMACEUTICAL MANUFACTURERS knew that THE STATE OF CALIFORNIA's Medicaid program was using the DEFENDANT PHARMACEUTICAL

MANUFACTURERS' false or fraudulent price and cost representations for purposes of paying or approving claims of the providers and suppliers of the DEFENDANT PHARMACEUTICAL MANUFACTURERS' specified pharmaceuticals; the DEFENDANT PHARMACEUTICAL MANUFACTURERS knew that sums of money paid by THE STATE to the providers and suppliers of the DEFENDANT PHARMACEUTICAL MANUFACTURERS' specified pharmaceuticals were grossly in excess of the amounts permitted by law; the DEFENDANT PHARMACEUTICAL MANUFACTURERS knew it was the obligation of THE STATE OF CALIFORNIA to recoup State funds paid in excess of the amounts permitted by law; the DEFENDANT PHARMACEUTICAL MANUFACTURERS, nevertheless, continued to cause the using and making of false records or statements of prices and costs for the specified pharmaceuticals that were grossly in excess of the reasonable amounts permitted by law; and the DEFENDANT PHARMACEUTICAL MANUFACTURERS thus concealed from THE STATE an obligation of the providers and suppliers of the DEFENDANT PHARMACEUTICAL MANUFACTURERS' specified pharmaceuticals to pay recoupment monies to THE STATE OF CALIFORNIA, resulting in great financial loss to THE STATE OF CALIFORNIA.

166. Because of the DEFENDANT PHARMACEUTICAL MANUFACTURERS' conduct as set forth in this Count, THE STATE OF California suffered actual damages in excess of One Hundred Million Dollars (\$100,000,000.00), all in violation of Cal. Gov. Code §12651(a)(7).

CASE	NO:	
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COUNT IV

CALIFORNIA FALSE CLAIMS ACT; CAUSING PRESENTATION OF FALSE CLAIMS; ILLEGAL REMUNERATION

167.	This is a civil action by the Plaintiff, THE STATE OF CALIFORNIA, and the
Qui Tam Pla	aintiff, VEN-A-CARE, on behalf of the STATE OF CALIFORNIA, against the
Defendants	
	DEY LABORATORIES
under the C	alifornia False Claims Act, Cal. Gov. Code §§12651(a)(1) and 12652(c)(1) et.
<u>seq</u> .	

168. Qui Tam Plaintiff realleges and incorporates by reference paragraphs 1 through 155 as if fully set forth herein and further alleges as follows:

- before January 1, 1988 to the present date, knew that the prices charged to their customers for the specified pharmaceuticals were significantly reduced in amount from the prices and costs represented by the DEFENDANT PHARMACEUTICAL MANUFACTURERS and upon which the Defendants knew the State's Medicaid claims would be approved and paid. Accordingly, the DEFENDANT PHARMACEUTICAL MANUFACTURERS have each knowingly offered or paid, or caused to be offered or paid, directly or indirectly, overtly or covertly, in cash or in kind, remuneration to their customers in the form of price reductions and/or in the form of illegal remuneration from the State's Medicaid Program to induce them to purchase, order or arrange or to recommend purchasing, arranging or ordering the specified pharmaceuticals for which the DEFENDANT PHARMACEUTICAL MANUFACTURERS knew that payment would be made, in whole or in part, by the State's Medicaid Program. Such financial inducement is specifically prohibited by Federal Statues 42 U.S.C. §1320a-7b(b)(2) and 18 U.S.C. §2.
- 170. The DEFENDANT PHARMACEUTICAL MANUFACTURERS knew that the State's Medicaid Program would not pay or approve claims for the specified pharmaceuticals if it were disclosed to the State's Medicaid Program that said claims were for amounts that included remuneration prohibited by Federal Statue 42 U.S.C. §1320a-7b(b)(2).
- 171. The DEFENDANT PHARMACEUTICAL MANUFACTURERS also knew that their customers, in presenting claims for the specified pharmaceuticals to the State's

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Medicaid Program, would not and did not disclose that the claim amounts included the remuneration prohibited by Federal Statue 42 U.S.C. §1320a-7b(b)(2).

- 172. The DEFENDANT PHARMACEUTICAL MANUFACTURERS' knowing and willful actions in arranging for their customers to receive remuneration prohibited by Federal Statue 42 U.S.C. §1320a-7b(b)(2), in causing the omission of material information from the claims, and in causing the failure to properly disclose and appropriately reflect the remuneration in the claims, caused the claims for the specified pharmaceuticals to be false claims and caused the claims to be presented to the State's Medicaid Program for payment and approval in violation of Cal. Gov. Code §12651(a)(1).
- 173. Because of the DEFENDANT PHARMACEUTICAL MANUFACTURERS' conduct as set forth in this Count, THE STATE OF CALIFORNIA suffered actual damages in excess of One Hundred Million Dollars (\$100,000,000.00) all in violation of Cal. Gov. Code §12651(a)(1).

COUNT V

CALIFORNIA FALSE CLAIMS ACT; CAUSING A FALSE RECORD OR STATEMENT TO BE MADE OR USED TO GET A FALSE CLAIM PAID OR APPROVED BY THE STATE OF CALIFORNIA: ILLEGAL REMUNERATION

174.	This is a civil action by the Plaintiff, THE STATE OF CALIFORNIA, and the
Qui Tam Pla	intiff, VEN-A-CARE, on behalf of THE STATE OF CALIFORNIA, against th
Defendants,	

CASE NO:
DEY LABORATORIES
under the California False Claims Act, Cal. Gov. Code §§12651(a)(2) and 12652(c)(1)
et. seq.

- 175. Qui Tam Plaintiff realleges and incorporates by reference paragraphs 1 through 155 as if fully set forth herein and further alleges as follows:
- 176. The DEFENDANT PHARMACEUTICAL MANUFACTURERS, from on or before January 1, 1988 to the present date, knew that the prices charged to their customers for the specified pharmaceuticals were significantly reduced in amount from the prices and costs represented by the DEFENDANT PHARMACEUTICAL MANUFACTURERS and upon which the Defendants knew the State's Medicaid claims would be approved and paid. Accordingly, the DEFENDANT PHARMACEUTICAL MANUFACTURERS have each knowingly offered or paid, or caused to be offered or paid, directly or indirectly, overtly or covertly, in cash or in kind, remuneration to their

CASE NO	:
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customers in the form of price reductions and/or in the form of illegal remuneration from the State's Medicaid Program to induce them to purchase, order or arrange or to recommend purchasing, arranging or ordering the specified pharmaceuticals for which the DEFENDANT PHARMACEUTICAL MANUFACTURERS knew that payment would be made, in whole or in part, by the State's Medicaid Program. Such financial inducement is specifically prohibited by Federal Statues 42 U.S.C. §1320a-7b(b)(2) and 18 U.S.C §2.

- 177. The DEFENDANT PHARMACEUTICAL MANUFACTURERS knew that the State's Medicaid Program would not pay or approve claims for the specified pharmaceuticals if it were disclosed to the State's Medicaid Program that said claims were for amounts that included remuneration prohibited by Federal Statue 42 U.S.C. §1320a-7b(b)(2).
- 178. The DEFENDANT PHARMACEUTICAL MANUFACTURERS also knew that their customers, in presenting claims for the specified pharmaceuticals to the State's Medicaid Program, would not and did not disclose that the claim amounts included the remuneration prohibited by 42 U.S.C. §1320a-7b(b)(2).
- 179. The DEFENDANT PHARMACEUTICAL MANUFACTURERS' knowing and willful actions in arranging for their customers to receive remuneration prohibited by 42 U.S.C. §1320a-7b(b)2, in causing the omission of material information from the claims, and in causing the failure to properly disclose and appropriately reflect the remuneration in the claims, caused false records or statements to be made and used to get false claims paid or approved by THE STATE for the specified pharmaceuticals. The DEFENDANT

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PHARMACEUTICAL MANUFACTURERS' actions herein caused said false records or statements to be made and used as prohibited by Cal. Gov. Code §12651(a)(2).

180. Because of the DEFENDANT PHARMACEUTICAL MANUFACTURERS' conduct as set forth in this Count, THE STATE OF CALIFORNIA suffered actual damages in excess of One Hundred Million Dollars (\$100,000,000.00), all in violation of Cal. Gov. Code §12651(a)(2).

PRAYER FOR RELIEF

WHEREFORE, the Qui Tam Plaintiff, on behalf of THE STATE OF CALIFORNIA, demands:

1.	That judgment be entered in its favor and against Defendants,
	DEY LABORATORIES;

with judgment to be entered against each Defendant for the amount of damages to the State's Medicaid Program arising from claims for each Defendant's respective specified pharmaceuticals; and from claims arising for those pharmaceuticals classified under the NDC numbers and HCPCS codes covering their specified pharmaceuticals, jointly and severally with such other defendants whose pharmaceuticals fall under said NDC numbers and HCPCS codes, as follows:

- A. On Count I (California False Claims Act; Causing Presentation of False
 Claims to the STATE OF CALIFORNIA) for triple the amount of THE
 STATE OF CALIFORNIA's damages, plus civil penalties of no more than
 TEN THOUSAND DOLLARS (\$10,000.00) for each false claim;
- B. On Count II (California False Claims Act; Causing False Records or Statements To Be Used To Get False Claims Paid By THE STATE OF CALIFORNIA) for triple the amount of THE STATE OF CALIFORNIA's damages plus civil penalties of no more than TEN THOUSAND DOLLARS (\$10,000.00) for each false record or statement;
- C. On Count III (California False Claims Act; causing False Statements To

 Be Used To conceal An Obligation To Pay Money To THE STATE OF

 CALIFORNIA) for triple the amount of THE STATE OF CALIFORNIA's

- damages plus civil penalties of no more than TEN THOUSAND DOLLARS (\$10,000.00) for each false record or statement used or made;
- D. On Count IV (California False Claims Act; Causing Presentation of False Claims; Illegal Remuneration) for triple the amount of THE STATE OF CALIFORNIA's damages, plus civil penalties of no more than TEN THOUSAND DOLLARS (\$10,000.00) for each false claim;
- E. On Count V (California False Claims Act; Causing A False Record Or Statement To Be Made Or Used To Get A False Claim Paid Or Approved by THE STATE OF CALIFORNIA; Illegal Remuneration) for triple the amount of THE STATE OF CALIFORNIA's damages plus civil penalties of no more than TEN THOUSAND DOLLARS (\$10,000.00) for each false record or statement; and
- 2. For all fees and costs of this civil action; and
- 3. For such other and further relief as the Court deems just and equitable.

Further, the Qui Tam Plaintiff, on its behalf, requests that it receive thirty percent (33%), or such other maximum amount as permitted by law, of the proceeds of this action or settlement of this action collected by THE STATE OF CALIFORNIA, plus an amount for reasonable expenses incurred, plus reasonable attorneys' fees and costs of this action. The Qui Tam Plaintiff requests that its percentage be based upon the total value recovered, including any amounts received from individuals or entities not parties to this action.

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DEMAND FOR JURY TRIAL

A jury trial is demanded in this case.

Respectfully submitted,

Facsimile:

Plaintiff, The State of California ex. rel. Ven-A-Care of the Florida Keys, Inc.

M. James Lorenz California Bar No: 038619 Lorenz, Alhadeff, Cannon & Rose, LLP 550 West "C" Street, 19th Floor San Diego, California 92101-3540 Telephone: (619) 231-8700 (619) 231-8323

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Telephone: (305) 577-0044 Facsimile: (305) 577-8545

CASE NO:	
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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this _	day of July, 1998, I caused an original
of this Complaint to be filed under seal ar	nd <u>in camera</u> for sixty (60) days and not to be
served on the Defendants named herein	or until further order of this Honorable Court.
I HEREBY CERTIFY that on this _	day of July, 1998, I caused a copy of
this Complaint and written disclosure of s	substantially all material evidence and
information the Qui Tam Plaintiff possess	to be served on the Attorney General of the
State of California the same day as the fil	ling of this Complaint by Certified Mail, Return
Receipt Requested.	
	Respectfully submitted,
	Respectionly submitted,
	M. James Lorenz
	California Bar No: 038619 Lorenz, Alhadeff, Cannon & Rose, LLP
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